REMARKS

Claims 1-17 remain in the application. Claims 1, 3, 6, 7, 10, 11, 12, 13, 14, 15, 16, and 17 are in independent form. The presently pending independent claims have been amended to place the present application in condition for allowance or at least in better condition for appeal. These claims have been amended in accordance with suggestions set forth in the outstanding Office Action and to further clarify the present invention.

Referring to the Office Action, claims 1-3, 11, 13, and 16 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. In response thereto, Applicants have amended the independent claims in accordance with suggestions set forth in the outstanding Office Action. Specifically, the Office Action holds that the scope of the claims is beyond peptides of known structure and/or function. The independent claims have been amended without prejudice to limited to peptides of known structure and function. Hence, reconsideration of the rejection is respectfully requested.

Claims 1-3, 11, 13, and 16 are also rejected under 35 U.S.C. § 112, first paragraph, for not reasonably providing enablement for a fusion protein that inhibits the function of any endogenously made protein and protect against any disease in a vertebrate. "The purpose of [the enablement] provision is to assure that the inventor provides sufficient information about the claimed invention that a person of skill in the field of the invention can make and use it without undue experimentation, relying on the patent specification and the knowledge in the art." *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991) (emphasis added). Further, "[t]he enablement requirement is met if the description enables any mode of making and using the claimed invention." *Engel Industries, Inc. v. Lockformer Co.*, 946 F.2d 1528 (Fed. Cir. 1991) (emphasis added).

In response ther to, Applicants have amended the claims without prejudice in order to expedite the allowance of the present application. Specifically, the claims have been limited to peptides of known structure and function, which are clearly supported by the specification. The specification is replete with examples of the types of peptides that can be used for the portions of the fusion protein responsible for the dual immune response. Both the activity of a peptide of known structure and function endogenously synthesized by the vertebrate are inhibited. A pathogenic infection in the vertebrate is also inhibited. (See, Page 11, Line 14 to Page 14, Line 28). Those of skill in the art know how to combine the peptides to form the fusion protein. Moreover, the specification explains in detail how to form or make the connection between the peptides (See, Page 8, lines14-27, and Page 15, Line 32 to Page 16, Line 4), corresponding vectors (See, Page 20, Lines 23-29; and Page 22, Line 23 to Page 26, Line 2), and corresponding transformed cells (See, Page 26, Line 5 to Page 28, line 5). The examples of the present application further explain in detail an embodiment of the present invention, which can be applied to any number of peptides known to those of skill in the art. Since enablement only requires the disclosure to explain "any mode of making and using the claimed invention." *Engel Industries, Inc. v. Lockformer Co.*, 946 F.2d 1528 (Fed. Cir. 1991) (emphasis added) and "routine experimentation does not constitute undue experimentation..." *Johns Hopkins University v. Cellpro, Inc.*, 152 F.3d 1342 (Fed. Cir. 1998), those of skill in the art can utilize their knowledge and the information disclosed in the present application to arrive at the claimed invention. Reconsideration of the rejection is respectfully requested.

Claims 1-17 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,684,145 to Van der Zee, et al. and U.S. Patent No. 5,684,145 to Mittal, et al. In response thereto, Applicants submit that the presently pending claims are not obvious in view of the cited prior art references.

A *prima facie* cas of obviousness requires fulfillment of three basic criteria. First, there must be some suggestion or motivation in either the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be reasonable expectation of success. Third, the prior art reference, or references when combined, must teach or suggest all of the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must be found in the prior art and not based on the disclosure of the Applicants' application. See, MPEP § 2142 and *In re Vaeck*, 947 F2d. 488 (Fed. Cir. 1991).

Obviousness can be only established by combining or modifying the teachings of the prior art to produce the claimed invention when there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See, *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988). Moreover, the burden lies with the Patent Office to explicitly make of record the factual underpinnings for a conclusion of obviousness.

> The Patent Examiner and the Board are deemed to have experience in the field of the invention; however, this experience, insofar as applied to the determination of patentability, must be applied from the viewpoint of 'the person having ordinary skill in the art to which said subject matter pertains,' the words of section 103. In finding the relevant facts, in assessing the significance of the prior art, and in making the ultimate determination of the issue of obviousness, the Examiner and the Board are presumed to act from this viewpoint. Thus, when they rely on what they assert to be general knowledge to negate patentability, that knowledge must be articulated and placed on the record. The failure to do so is not consistent with either effective administrative procedure or effective judicial review. The Board cannot rely on conclusory statements when dealing with particular combinations of prior art and specific claims, but must set forth the rationale on which it relies. *In re Lee*, 277 F.3d 1338, 1345 (Fed. Cir. 2002).

With regard to the present application, in order to establish a *prima facie* case of obviousness, a fact-based explanation is needed as to why one of ordinary skill in the art at the time the invention was made would have been

motivated to substitute the strong immunogenicity of BHV-1 gD taught by Mittal, et al. with the *E. coli* P-fimbrial subunit portion of the hybrid protein disclosed in the Van der Zee, et al. reference to evoke an immune response against GnRH and protect against BHV-1 infection. One of ordinary skill in the art would not know, or have a reasonable expectation of success, in producing the claimed invention since there is no reason to believe that the combined protein would have active immunogenic sites once the strongly immunogenic BHV-1 gD is combined with the antigenic determinant of GnRH of the protein disclosed in the Van der Zee, et al. reference. In fact, there is no specific factual evidence that two specific immune responses would be directed against two specific immunogens. For example, binding of the proteins could affect or functionally alter immunogenic sites, alter structural conformation of either or both peptides, destroy functional portions of either or both peptides, or make other unexpected alternatives that could negate the specifically claimed dual function of the present invention. It is mere speculation that the combination of the strong immunogen disclosed in the Mittal, et al. reference and the protein disclosed in the Van der Zee, et al. reference would result in an active protein capable of eliciting a specific and independent dual immunogenic response.

The cited prior art references merely teach components of the claimed invention. "One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." *In re Fine*, 837 F2d. 1071 (Fed. Cir. 1988). Moreover, "[d]etermination of obviousness cannot be based on the hindsight combination of components selectively called from the prior art to fit the parameters of the patented invention." *ATD Corp. v. Lydall, Inc.*, 159 F3d. 534 (Fed. Cir. 1998).

The obviousness rejection as set forth in the outstanding Office Action is based on impermissible hindsight. The components of the claimed invention are merely mentioned in the cited prior art references and there is no suggestion in the prior art to combine the teachings disclosed in the prior art references so that the d sired function of the presently claimed invention could be achieved. There is no suggestion in the prior art references, nor

would one b motivated to combine these references, as set forth in the outstanding Office Action. There is no factual basis set forth in the outstanding office action for a reasonable expectation of success to do so. One would have to ignore the critical teachings of the prior art references in order to combine select features of the references to derive the presently claimed invention. Such picking and choosing can be only done through improper hindsight.

As a result of these claimed differences over the prior art and lack of suggestion and motivation to modify the references or to combine the references, the present invention is patentably distinct. Reconsideration of the obviousness rejection is respectfully requested.

The remaining dependent claims not discussed above are ultimately dependent upon at least one of the independent claims discussed above. No prior art reference makes up for the deficiencies of that reference as applied against the independent claims as no prior art reference discloses or suggests the invention as set forth in the claims as discussed in detail above.

It is respectfully submitted that the present Amendment places the application in condition for allowance as it removes all remaining issues in dispute. Specifically, the Amendment follows suggestions set forth in the Office Action and clarifies the present invention. As a result, no remaining issues are in dispute. Since there is no prior art cited against any of these claims, it is respectfully submitted that all of the claims are in condition for allowance. It is also respectfully submitted that the present Amendment places the application in condition for appeal. The claims have not been made broader in scope, thereby requiring no further searching, nor do the claims raise any new issues. In fact, all claims now include limitations of previously pending claims and were therefore previously searched.

It is respectfully requested that the present Amendment be entered in order to place the application in condition for allowance or at least in better condition for appeal. The application is placed in condition for allowance as it addresses and resolves each and every issue that remains pending. The claims have also been amended to clearly distinguish them over the prior art.

The application is made at least in better condition for appeal as the Amendment removes any issues, thereby simplifying the issues on appeal. That is, each and every rejection has been overcome. Hence, it is respectfully requested that the Amendment be entered.

Applicants respectfully request to be contacted by telephone if any remaining issues exist.

The Commissioner is authorized to charge any fee or credit any overpayment in connection with this communication to our Deposit Account No. 11-1449.

Respectfully submitted,

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CERTIFICATE OF MAILING/TRANSMISSION

I hereby certify that this correspondence is being transmitted by facsimile to the Patent and Trademark Office at (703) 308-4242 on November 4, 2002.

Connie Herty

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

1. (Amended) A fusion protein for producing a dual immune response in a vertebrate, which fusion protein comprises:

(a) a first proteinaceous portion analogous to all or part of a peptide of known structure and function endogenously synthesized within the vertebrate, the activity of which peptide is to be inhibited within the vertebrate, and which proteinaceous portion by itself is incapable of eliciting an effective immunoinhibitory response in said vertebrate; connected to

(b) a second proteinaceous portion analogous to all or part of an immunogen from a pathogen, which pathogen is capable of pathogenically infecting the vertebrate;

the portion (b) causing the vertebrate's immune system to recognize the portion (a) and produce a response that:

(i) inhibits the activity of the peptide of known structure and function endogenously synthesized within the vertebrate; and

(ii) protects the veretebrate from known infection caused by the pathogen, when the vertebrate is vaccinated with an effective amount of the fusion protein.

3. (Amended) A fusion protein for producing an immune response in a vertebrate, which fusion protein comprises:

(a) a first proteinaceous portion analogous to all or part of a peptide of known structure and function, the activity of which is to be inhibited within the vertebrate, and which proteinaceous portion by itself is incapable of eliciting an effective immunoinhibitory response in [said] the vertebrate; connected to

(b) a second proteinaceous portion analogous to all or part of a BHV-1 antigen;

the second proteinaceous portion (b) causing the vertebrate's immune system to recognize the first proteinaceous portion (a) and produce an immune response capable of inhibiting the activity of [the] said peptide within the vertebrate when the vertebrate is vaccinated with an effective amount of the fusion protein.

11. (Twice Amended) A dual-function vaccine which comprises a fusion protein according to claim 1, a vector according to claim 7, or a transformed cell according to claim 10, in an amount effective to I) inhibit the activity of the peptide of known structure and function from which portion (a) of the fusion protein is derived, and II) to protect against known infection caused by the pathogen from which portion (b) of the fusion protein is derived; and a carrier acceptable for pharmaceutical or veterinary use.